REMARKS

Claims 1-13 were pending. Applicants amend claim 1 above. Accordingly, claims 1-13 are being examined.

Support for amended claim 1 may be found in the specification as originally filed at page 6, lines 27-30.

CLAIM OBJECTION

The Examiner objected to claim for its recitation of "V-1." The Examiner is requesting Applicants to write out the acronym.

In response, applicants have complied.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. §102(b)

In items 3-4, at page 2 of the Office Action, the Office rejects claims 1-4, 6 and 13 under 35 U.S.C. §102(b), as allegedly anticipated by Lindberg et al. (of record)

Applicants respectfully disagree for the reasons that follow.

The Legal Standard for Novelty:

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Each and every element of the claimed invention must be disclosed in a single prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing

the invention in possession of the public. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied* 469 U.S. 851, 105 S. Ct. 172 (1984); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576-7 (Fed. Cir. 1991), *clarified, on recons.*, 1991 U.S.App. LEXIS 33,486 (Fed. Cir. 1991). The absence of even a single element from a prior art reference negates anticipation. *Atlas Powder Co. v. E. I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).

Applicants Have Met the Legal Standard for Novelty:

Lindbergh does not expressly or inherently anticipate the presently claimed methods:

Lindberg teaches administering lysine vasopressin (LV) to patients which resulted in fewer hypotensive episodes. Lindberg states that this suggests that LV may be efficacious in alleviating refractory hemodialysis induced hypotension (HIH).

However, Lindberg does not expressly teach reducing excess extracellular fluid in a subject undergoing hemodialysis. Moreover, Lindberg does not expressly teach maintaining blood pressure during hemodialysis.

Lindberg does not inherently teach the claimed methods because the claimed methods are directed to reducing excess extracellular fluid. By simply showing fewer hypotensive episodes, Lindberg does not necessarily effect the claimed methods for reducing excess extracellular fluid.

REJECTION OF THE CLAIMS UNDER 35 U.S.C. §103(a)

In items 5-6, at page 3 of the Office Action, the Office rejects claims 5 and 7-12 under 35 U.S.C. §103(a), as allegedly unpatentable over Lindberg et al. (of record)

Applicants respectfully disagree for the reasons that follow.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination, and the reasonable expectation of success, must both be found in the prior art, not in the Applicant's disclosure (In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

In this case, the prior art does not teach or suggest all the limitations of claims 5 and 7-12. Further, even if the prior art did teach or suggest all claim limitation, the reference would fail because the prior art reference does not provide reasonable expectation of success to achieve the claimed invention.

As discussed above, Lindberg does not teach or suggest reducing excess extracellular fluid in a subject undergoing hemodialysis using a vasopressin (V-1) receptor agonist. Accordingly, it would not have been obvious to substitute one vasopressin agonist for another, at any dosage, let alone the claimed dosages.

No fee, other than the extension fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, Applicants hereby authorize the Patent Office to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Sarah B. Adriano
Registration No. 34,470
SaraLynn Mandel
Registration No. 31,853
Mandel & Adriano
55 S. Lake Avenue, Suite 710
Pasadena, California 91101
626/395-7801
Customer No. 26,941